

July 10, 2003

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-09

Subject: Issuance of Licenses

To: Biologics Licenses, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated during the months of April, May and June 2003. These do not include those licenses reissued to update pertinent information. A product license or permit for distribution and sale has been issued for each of the following:

| True Name | Product Code | Establishment/ Permittee | Date |
|-----------------------------------------------------------------------------------------------------|---------------------|--------------------------------------------------------|-------------|
| Avian Reovirus Vaccine, Killed Virus | 1045.20 | Biomune Co., Est. 368 | 05/16/2003 |
| Avian Reovirus Vaccine, Killed Virus | 1045.30 | Biomune Co., Est. 368 | 05/12/2003 |
| Bursal Disease-Reovirus Vaccine, Standard and Variant, Killed Virus | 12D5.E0 | Biomune Co., Est. 368 | 05/12/2003 |
| Bursal Disease-Newcastle Disease-Reovirus Vaccine, Standard and Variant, Killed Virus | 12P5.E0 | Biomune Co., Est. 368 | 05/16/2003 |
| Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus | 15D5.R0 | Wyeth, Est. 112 | 06/23/2003 |
| Newcastle Disease Vaccine, VG/GA Strain, Live Virus | 1701.10 | Merial Select, Inc., Est. 279 | 05/07/2003 |
| Newcastle Disease Vaccine, B ₁ Type, LaSota Strain, Live Virus | 1721.0A | Lohmann Animal Health International, Est. 196 | 05/13/2003 |
| Avian Encephalomyelitis-Fowl Pox-Mycoplasma Gallisepticum Vaccine, Live Virus, Live Fowl Pox Vector | 1D61.R0 | Biomune Co., Est. 368 | 06/09/2003 |

| True Name | Product Code | Establishment/ Permittee | Date |
|-----------------------------------------------------------------------------------------------------------------------------|--------------|---------------------------------------------------|------------|
| Erysipelothrix Rhusiopathiae-Haemophilus Parasuis Bacterin | 2646.01 | Boehringer Ingelheim Vetmedica, Est. 124 | 06/26/2003 |
| Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4835.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4835.46 | Wyeth, Est. 112 | 04/21/2003 |
| Encephalomyelitis-Rhinopneumonitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4844.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis-Rhinopneumonitis- Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4845.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis-Rhinopneumonitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid | 4846.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis-Rhinopneumonitis- Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid | 4847.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4865.25 | Wyeth, Est. 112 | 04/21/2003 |
| Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid | 4865.26 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid | 4867.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis-Influenza Vaccine, Eastern, Western, and Venezuelan, Killed Virus, Tetanus Toxoid | 4875.21 | Wyeth, Est. 112 | 06/20/2003 |
| Encephalomyelitis Vaccine, Eastern and Western, Killed Virus, Ehrlichia Risticii- Tetanus Bacterin-Toxoid | 4B35.41 | Wyeth, Est. 112 | 04/21/2003 |
| Leptospira Hardjo Bacterin | B6M7.01 | Biocor Animal Health, Est. 462 | 06/18/2003 |
| Newcastle Disease Virus Antibody, Chicken Origin | C710.00 | Charles River Laboratories, Inc., Est. 344 | 05/13/2003 |

The following product license for ARKO Laboratories, Ltd., Est. 337, was terminated without prejudice on April 28, 2003:

Mycoplasma Gallisepticum Vaccine, Live Culture, Code 1751.00

The following product licenses for Boehringer Ingelheim Vetmedica, Est. 124, were terminated without prejudice on June 2, 2003:

Mycoplasma Hyopneumoniae Bacterin, Code 2775.04

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Code 4975.20

The following product licenses for Wyeth, Est. 112, were terminated without prejudice on May 13, 2003:

Rabies Vaccine, Killed Virus, Code 1905.51

Microsporum Canis Vaccine, Killed Fungus, Code 1M05.00

The following product licenses for Micro Technologies, Inc., Est. 403, were terminated without prejudice on June 10, 2003:

Aeromonas Salmonicida Bacterin, Code 2035.00

Aeromonas Salmonicida-Vibrio Anguillarum-Salmonicida Bacterin,
Code 2137.00

The following product licenses for Novartis Animal Vaccines, Inc., Est. 303, were terminated without prejudice on April 4, 2003:

Transmissible Gastroenteritis Vaccine, Modified Live Virus, Code 1961.20

Transmissible Gastroenteritis Vaccine, Killed Virus, Code 1965.20

Campylobacter Fetus-Escherichia Coli Bacterin, Code 2122.00

Escherichia Coli Bacterin, Code 2648.A7

Escherichia Coli Bacterin, Code 2648.09

Escherichia Coli Bacterin, Code 2648.10

Escherichia Coli Bacterin, Code 2648.65

Moraxella Bovis Bacterin, Code 2772.01

Streptococcus Suis Bacterin, Code 2840.00

Streptococcus Equisimilis Antibody, Equine Origin, Code 3860.00

Streptococcus Equisimilis-Suis Antibody, Equine Orgin, Code 3865.00

Streptococcus Suis Antibody, Equine Origin, Code 3870.00

Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens
Types C&D Bacterin-Toxoid, Code 7160.00

Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C&D
Bacterin-Toxoid, Code 7410.00

The following product licenses for Schering-Plough Animal Health, Est. 226, were terminated without prejudice on May 21, 2003:

Bursal Disease Vaccine, Standard & Variant, Killed Virus, Code 12B5.40

Bursal Disease, Newcastle Disease Vaccine, Killed Virus, Standard & Variant,
Code 12G5.41

Bursal Disease, Newcastle Disease, Bronchitis Vaccine, Standard & Variant,
Mass Type, Killed Virus, Code 12J5.60

Marek's Disease Vaccine, Serotype 2, Live Virus, Code 1631.00

Marek's Disease Vaccine, Serotype 3, Live Virus, Code 1641.00

Newcastle Disease Vaccine, Killed Virus, Code 1705.10

Newcastle Disease Vaccine, Killed Virus, Code 1705.11

Newcastle-Bronchitis Vaccine, B1 Type, B1 Strain, Mass & Conn Type,
Live Virus, Code 1761.1X

Newcastle-Bronchitis Vaccine, Killed Virus, Code 1761.12

Newcastle-Bronchitis Vaccine, Mass Type, Killed Virus, Code 1775.10

Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

Richard E. Hill, Jr.

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